Supplemental Guidance for Risk Assessments

This document provides risk assessors and Approved Professionals guidance related to the performance of human health and ecological risk assessments for contaminated sites in British Columbia. It supplements existing provisions in protocols under the *Environmental Management Act* (the Act) for risk assessment and is subject to change as our risk assessment methodology, policy and guidance is updated.

Screening level risk assessment

Protocol 13, "Screening Level Risk Assessment" (SLRA) is intended to evaluate whether contamination at a specific site meets or exceeds benchmark screening criteria for human health and the environment. The SLRA process involves a simple default assessment of key exposure pathways and receptors.

Contaminated sites that meet SLRA benchmark screening criteria are considered to satisfy Contaminated Sites Regulation (CSR) risk-based standards. No further risk assessment or remediation is required at such sites as long as site conditions do not change. Ongoing environmental monitoring, to ensure maintenance of site conditions, may be necessary at SLRA assessed sites.

Risk assessors are cautioned that the use of SLRA is subject to precluding conditions, and cannot be used at high risk sites or at sites where contaminated vapours, surface water, or sediments require risk assessment.

Quantitative risk assessment

Human health risk assessment

Detailed human health risk assessments under the Act should include all applicable human receptors known, or reasonably inferred, to be present at a site, including uniquely sensitive or exposed human receptor subgroups such as:

a) susceptible age groups (e.g. children and the aged),

b) hypersensitive individuals (e.g. pregnant women, PICA children, etc.),

c) vulnerable individuals known to suffer compromised health impacts (e.g. chemical hypersensitivity, impaired pulmonary function, immunodeficiency, etc.), and

d) uniquely exposed individuals (e.g. subsistence consumers).

Further, provision of rationale for site-specific inclusion or exclusion of sensitive receptors is expected in all detailed human health risk assessments.

Note

It is not required to include acute/subchronic exposures for subsurface (utility, trench, and construction) workers in quantitative human health risk assessments for CSR regulatory purposes. Worker health and safety is the responsibility of WorkSafeBC under the *Workers Compensation Act* and the Occupational Health and Safety Regulation. WorkSafeBC requirements must be met at contaminated sites. Operative chronic (>90 days) occupational exposure pathways do need to be included for subsurface workers in risk assessments for CSR regulatory purposes.

Deterministic risk assessment

General Guidance

For general use in human health deterministic risk assessment, the ministry recommends use of the following Health Canada, Federal Contaminated Site Risk Assessment in Canada, guidance:

- *Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (2012),*
- *Part II: Health Canada Toxicological Reference Values (TRVs), Version 2.0 (2010),*
- *Part III: Guidance on Peer Review of Human Health Risk Assessments for Federal Contaminated Sites in Canada, Version 2.0 (2010),*
- *Part IV: Spreadsheet Tool for Human Health Preliminary Quantitative Risk Assessment (2009).* available on request from cs-sc@hc-sc.gc.ca,
- *Part V: Guidance on Complex Human Health Detailed Quantitative Risk Assessment for Chemicals ($DQRA_{CHEM}$) (2010),*
- *Part VI: Guidance on Human Health Detailed Quantitative Radiological Risk Assessment for Chemicals ($DQRA_{RAD}$) (2010),*
- *Supplemental Guidance on Human Health Risk for Country Foods (HHRA Foods) (2010),* and
- *Supplemental Guidance Checklist for Peer Review of Detailed Human Health Risk Assessments (HHRA), 2010.*

Furthermore, the ministry strongly recommends use of the: critical human receptors, physiological parameters, exposure routes, exposure scenario assumptions and associated toxicological equations provided in Health Canada, *Federal Contaminated Site Risk Assessment In Canada Part I: Guidance on Human Health Preliminary Quantitative Risk Assessment (PQRA), Version 2.0 (2012)* guidance:

- *Table 2. Problem Formulation Checklist,*
- *Table 3. Recommended Human Receptors and Their Characteristics for Preliminary Quantitative Risk Assessments,*
- *Table 4. Exposure Duration and Frequency Assumptions for Preliminary Quantitative Risk Assessments,*
- *Table 5. Recommended General Equations Dose Estimation,*
- *Table 7. Potency Equivalence Factors for Carcinogenic Polycyclic Aromatic Hydrocarbons,* and
- *Table 8.Toxic Equivalency Factors for Dioxins, Furans, and Certain Polychlorinated Biphenyls.*

And the absorption factors provided in *Part II: Health Canada Toxicological Reference Values (TRVs), Version 2.0 (2010)* guidance:

- *Table 3. Dermal Relative Absorption Factors (RAF_{dermal}) of Selected Substances.*

Other Health Canada documents and versions in addition to those listed above may be used if adequate rationale is provided for their use.

Note
In cases where ministry policy contradicts the guidance documents listed above, ministry policy takes precedence over the guidance. In these circumstances contact the ministry for further advice.

Exposure Parameters

For exposure parameters, equations and scenarios not in Health Canada guidance, the following U.S. Environmental Protection Agency (US EPA) guidance is recommended:

- *Risk Assessment Guidance for Superfund (RAGS) Part A,*
- *Supplement to RAGS, Volume 1, Part A: Community Involvement in Superfund Risk Assessments (1999),*
- *Risk Assessment Guidance for Superfund (RAGS) Part B,*
- *Risk Assessment Guidance for Superfund (RAGS) Part C,*
- *Risk Assessment Guidance for Superfund (RAGS): Part D,*
- *Risk Assessment Guidance for Superfund (RAGS), Volume 1: Health Evaluation*

Manual (Part E, Supplemental Guidance for Dermal Risk Assessment) Interim,

- *Risk Assessment Guidance for Superfund (RAGS), Volume 1: Human Health Evaluation Manual (Part F, Supplemental Guidance for Inhalation Risk Assessment)*,
- *Guidelines for Carcinogen Risk Assessment*,
- *Guidelines for Reproductive Toxicity Risk Assessment*,
- *Guidelines for Neurotoxicity Risk Assessment*.
- *Guidelines for Developmental Toxicity Risk Assessment*,
- *Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures*,
- *Exposure Factors Handbook*, and
- *Child-Specific Exposure Factors Handbook.*

Guidance on Soil Vapour Assessment

For assessments concerned with determining risk and hazard associated with exposure to soil vapours, the ministry recommends use of the following guidance:

- Ministry of Environment. *Technical Guidance 4, "Vapour Investigation and Remediation"*,
- Health Canada. *Federal Contaminated Sites Risk Assessment in Canada: Guidance for Soil Vapour Intrusion Assessment at Contaminated Sites,* and
- Science Advisory Board for Contaminated Sites in British Columbia: *Report on Screening Level Risk Assessment, SLRA Level 1 and SLRA Level 2.*

Carcinogenic Classification

Evaluation of both non-carcinogenic and carcinogenic effects related to exposure to contamination at a site is a necessary component of detailed human health risk assessment performed under the Act.

Potential for carcinogenicity should be based on substance specific classifications from the following preferred order of agencies:

1. Health Canada: *Federal Contaminated Site Risk Assessment in Canada Part II: Health Canada Toxicological Reference Values (TRVs), Version 2.0*,
2. US EPA: *Integrated Risk Information System (IRIS)*, Group A and B1 listed substances,
3. UN World Health Organization, International Agency for Research on Cancer (IARC): *Agents Classified by the IARC Monographs, Volumes 1 – 100*, Group 1 and 2A listed substances, and
4. US National Toxicology Program: *Report on Carcinogens*, Group 1 and 2 listed substances.

Source and Selection of Human Health Toxicity Reference Values (TRVs)

Toxicity Reference Values (TRVs) include: Acceptable Daily Intake (ADI), Tolerable Daily Intake (TDI), Reference Dose (RfD), Reference Concentration (RfC), Benchmark Dose (BMD), Minimum Risk Level (MRL), Cancer Slope Factor (CSF), and Cancer Unit Risk (UR), among others.

The ministry acknowledges that TRVs from Canadian agencies generally incorporate Canadian, as opposed to foreign, policy assumptions and values. Further, the ministry also recognizes that Canadian agency TRVs are widely used within Canada for public health and environmental decision making outside of the contaminated sites field, and that use of Canadian TRVs will generally provide for greater consistency between contaminated sites risk assessments and risk assessments conducted on food, water and air. However, compared to TRVs from Canadian agencies, TRVs obtained from American environmental agencies are typically subject to more frequent peer review, revision and updating. In addition, US EPA TRVs rather than Canadian agency TRVs have been used by the ministry in setting most of the numerical standards of the Regulation.

In consideration of the above, the ministry recommends preferential use of US EPA: *Integrated Risk Information System (IRIS)* toxicity reference values in human health risk assessment, for all but the following:

1. chlorinated dioxins and furans
2. PCBs
3. lead
4. methyl mercury

For the above four substances and classes of substances, the ministry recommends use of the most recently published or publicly available Health Canada toxicity reference values for human health risk assessment.

Supplemental Agency Sources for Human Health TRVs
Where US EPA or Health Canada TRVs are lacking for a substance, use of human health toxicity reference values from the following supplemental sources may be considered:

- US Agency for Toxic Substances and Disease Registry: *ATSDR Toxic Substances Portal*,
- California Environmental Protection Agency: *Toxic Criteria Database*,
- Netherlands National Institute of Public Health and the Environment: *Re-evaluation of Human Toxicological Maximum Permissible Risk Levels*,
- US EPA, Region 9: *Regional Screening Levels (Formerly PRGs)*,
- US EPA, Region 9: *Preliminary Remediation Goals Table (2004)*, and
- UN World Health Organization: *International Programme on Chemical Safety, INCHEM.*

The ministry expects selection of an TRV from one of the supplemental agency sources listed above, to be based on the following criteria:

a) existence of a comprehensive and contemporary published science assessment on which the TRV is based,
b) extent of supporting rationale and documentation pertaining to the scientific derivation of the TRV, and
c) extent and rigor of scientific peer review provided for the TRV.

In addition, the ministry expects the rationale for selection of a supplemental TRV to be fully documented in any risk assessment in which a supplemental TRV is used.

Use of de novo derived Human Health TRVs
In the case where no credible human health TRV can be found, a *de novo* TRV may be derived based on the scientific literature related to the toxicity of the substance.

Hazard index and additive risks
A hazard index needs to be calculated for:

- each substance over all operable exposure pathways (regardless of whether substance concentrations exceed CSR standards in all exposure media), unless toxicity is pathway specific, and
- each group of substances sharing a mechanism of toxicity and a target organ, including structurally related carcinogenic substances (e.g. PAHs, PCBs, PCDDs and PCDFs).

Probabilistic risk assessment

General Guidance
Probabilistic human health risk assessment methods can often provide better information on the variability and uncertainty of risks.

For use in probabilistic risk assessment, the ministry recommends use of the following general US EPA risk assessment guidance:

- *Risk Assessment Guidance for Superfund (RAGS) Volume III - Part A: Process for Conducting Probabilistic Risk Assessment (2001)*;
- *Guiding Principles for Monte Carlo Analysis.*

When probabilistic methods are used, the ministry expects that rationale related to the selection of input parameter distributions and their applicability to British Columbia will be adequately documented.

Policy decisions

Drinking Water

Where site contaminated water is used as a drinking water source, (i.e., where a current drinking water exposure pathway is considered to be complete or operative), the ministry expects complete assessment of risks and hazards associated with the drinking water pathway (including fully documented exposure risk calculations) to be provided in the risk assessment for the site.

If the future drinking water exposure pathway is considered incomplete or inoperative (e.g. a community water supply is present as an alternate drinking water source, all site impacted drinking water wells have been decommissioned, or the risk management approach for the site is ongoing prohibition of use of site impacted water as drinking water), exposure risk calculations and associated risk estimates for the future drinking water pathway need not be included in the risk assessment for the site.

However, risk assessors are cautioned that the ministry also expects the risk assessment to include a statement that "future drinking water risks were not calculated" and provide full documentation of the rationale by which the future drinking water pathway was determined to be incomplete or inoperative.

Further guidance related to consideration of the drinking water pathway is provided in:

- *Technical Guidance 6, "Water Use Determination".*

Ecological risk assessment

General guidance

The primary goal of ecological risk assessment and/or ecological risk management is to ensure the continued presence, or successful re-introduction, of a biologically diverse, functional, self-sustaining, and interdependent community or ecosystem as an essential component of the remediation of contaminated sites in British Columbia.

The following ministry protocols and technical guidance apply to the performance of ecological risk assessments for contaminated sites in British Columbia:

- *Protocol 1, "Recommended Guidance and Checklist for Tier 1 Ecological Risk Assessment of Contaminated Sites in British Columbia",*
- *Protocol 20, "Detailed Ecological Risk Assessment".*
- *Tier 1 "Ecological Risk Assessment Policy Decision Summary",*
- *Technical Guidance 15, "Concentration Limits for the Protection of Aquatic Receiving Environments",* and
- *Technical Guidance 19, "Assessing and Managing Contaminated Sediments".*

The ministry also recommends consideration of the following guidance:

- Science Advisory Board for Contaminated Sites in British Columbia: *Detailed Ecological Risk Assessment (DERA) in British Columbia Technical Guidance. September 2008.*

Note

Despite the primary focus on assessing effects and impacts at the community, population or species level in ecological risk assessment, in some circumstances assessment at the individual organism level may be required. For example, some applicable legislation (e.g., Canadian Federal *Species at Risk Act* and B.C. *Wildlife Act*) requires protection at the level of the individual organism for rare and endangered species. In addition, assessment of habitat considered critical to support rare and endangered species or individuals may be needed.

Exposure pathways

Note
The inhalation pathway of exposure is not usually evaluated for ecological receptors unless site-specific conditions indicate that the pathway can be considered the primary exposure route for a population of a species, or if an individual of a rare and endangered species frequents or resides (e.g., burrows, hibernates, etc.) at the site.

Exposure parameters

For relevant ecological exposure parameters, the ministry recommends use of the following sources:

- US EPA: *Wildlife Exposure Factors Handbook*,
- California Environmental Protection Agency: *California Wildlife Exposure Factor and Toxicity Database*,
- US Geological Survey: *Wildlife and Contaminants Online,*
- Environment Canada: *FCSAP Ecological Risk Assessment Guidance, Standardization of Wildlife Receptor Characteristics (March 2012),* and
- California Department of Toxic Substances Control: *Guidance for Ecological Risk Assessments (EcoNOTES).*

In addition, relevant information from other jurisdictions and pertinent peer reviewed scientific literature may be used to supplement the above sources of ecological exposure parameters. In such cases, the rationale related to the selection of a supplemental ecological exposure parameter should be included in the ecological risk assessment report.

Toxicity profiles

For detailed ecological risk assessment, it is considered common practise that toxicity profiles are provided for each of the contaminants to be evaluated. At a minimum, such ecological toxicity profiles should include the following information:

a) toxic effects expected from exposure,
b) sensitivities of the different receptor groups exposed, and
c) the range of toxicities reported in the scientific literature for similar species to those present at the site under assessment.

These toxicity profiles should form the basis for the selection of appropriate ecological benchmarks to be used in the toxicity assessment component of the ecological risk assessment.

Ecological benchmarks – EcoTRVs

The ministry supports the use of quantitative ecological toxicity benchmarks such as Ecological Toxicity Reference Values (EcoTRVs) based on contaminant: intake, dose, tissue residues, and concentrations in environmental media to which an organism is exposed.

The use of specified effects levels such as: Effective Dose, Lethal Dose, Effective Concentration or Lethal Concentration, for x percent of exposed organisms (i.e. EDx, LDx, ECx or LCx values, respectively) for the estimation of risks to ecological receptors at the population/species level is generally preferred. Ecological risks are acceptable if the effects levels at the site are less than or equal to the specified effects level for the particular land use applicable at the site.

The ministry does not recommend the use of: No Observed (Adverse) Effect Levels (NO(A)ELs), No Observed (Adverse) Effect Concentrations (NO(A)ECs), Lowest Observed (Adverse) Effect Levels (LO(A)ELs), or Lowest Observed (Adverse) Effect Concentrations (LO(A)ECs) and similarly derived benchmarks; unless no other alternative benchmark can be found for a site.

For many contaminants, ministry preferred ecological benchmarks may not be readily available. In these cases, EcoTRVs will typically need to be calculated. EcoTRVs are

considered to be the ecological equivalent of calculating a human health reference dose (RfD).

EcoTRVs are acceptable for use as ecologically relevant benchmarks in ecological risk assessment with the caveat that ecological risk assessments are designed to protect species at the population, rather than at the individual organism level. The types of ecological effect endpoints that typically need to be addressed at the population level for non-endangered species include acute (e.g., toxicity and lethality) and chronic processes (e.g., reproductive, growth and maintenance, and critical developmental).

Note
Carcinogenicity is not usually selected as a chronic ecological effect endpoint unless the rate of cancer incidence is sufficient to threaten survival at the population level. However, if a particular organism warrants protection at the level of the individual (e.g., an individual of a rare and endangered species); cancer can be an appropriate chronic effect endpoint for that individual and can be considered, if data is available and adequate for assessment.

Source and selection of EcoTRVs

In consideration of the above, the ministry recommends preferential use of the US EPA ecological soil screening levels (*EcoSSLs)* as terrestrial EcoTRVs, and use of the BC Ministry of Environment: *Water Quality Guidelines* (i.e. the selected TRV for guideline derivation as specified in the Technical Appendix) as aquatic EcoTRVs.

Supplemental Agency Sources for Eco TRVs

Where EcoTRVs from the preferred sources are lacking for a substance, use of EcoTRVs from the following supplemental sources may be considered:

- US EPA: *ECOTOX Database*,
- Oak Ridge National Laboratory: *The Risk Assessment Information System, Ecological Benchmark Tool*,
- California Environmental Protection Agency: *California Wildlife Exposure Factor and Toxicity Database*,
- US EPA, Region 9: *Biological Technical Assistance Group (BTAG) Recommended Toxicity Reference Values for Mammals*,
- US Geological Survey: *Wildlife and Contaminants Online,*
- Centre d'Expertise en Analyse Environnementale du Québec: *Valeurs de Référence pur les Récepteurs Terrestres*, and
- CCME: *Canadian Tissue Residue Guidelines for the Protection of Wildlife Consumers of Aquatic Biota*.

The ministry expects selection of the most stringent applicable EcoTRV from the supplemental agency sources listed above, unless it can be shown by the risk assessor that an alternate value is more appropriate based on:

a) the existence of a more comprehensive and contemporary published scientific assessment,
b) enhanced relevance (study design, exposure route, etc.) to the site,
c) enhanced scientific credibility, or
d) greater extent of supporting rationale and documentation.

Selected EcoTRVs should be accompanied by a citation and documentation of the ecological effect endpoint upon which the value is based.

Use of *de novo* derived EcoTRVs

In the case where no credible ecological benchmark or EcoTRV can be found, a *de novo* EcoTRV may be derived based on:

a) the scientific literature related to the ecotoxicity of the substance, or
b) ecotoxicological experimental data obtained for the substance on a site specific basis (e.g., *in-situ* bioassay data obtained for a site).

Generally, the ministry discourages the use of arbitrary uncertainty factors in *de novo* TRV derivation. However, if data are limited and/or risk assessors are required to extrapolate among taxonomic groups, incorporation of an uncertainty factor may be warranted.

The ministry also recommends consideration of the following guidance:

- US EPA: *Guidance for Developing Ecological Soil Screening Levels (Eco-SSLs), Eco-SSL Standard Operating Procedure #6: Derivation of Wildlife Toxicity Reference Value (TRV) (June 2007),* and
- Environment Canada: *FCSAP Supplemental Guidance for Ecological Risk Assessment, Selection or Development of Site-Specific Toxicity Reference Values (June 2010).* Available on request from FCSAP.PASCF@ec.gc.ca.

Hazard index

A hazard index needs to be calculated for each substance exceeding a numerical standard at the site over all exposure media (regardless of whether substance concentrations exceed CSR standards in all exposure media).

Toxicity testing

The ministry recommends toxicity test methods established by the following agencies for use in ecological risk assessment:

- BC Ministry of Environment: *British Columbia Environmental Laboratory Manual (Part C),*
- Environment Canada: *Biological Test Method Series,*
- US EPA: *Whole Effluent Toxicity – Methods for Measuring Acute Toxicity to Freshwater and Marine Organisms,*
- US EPA, *Office of Chemical Safety and Pollution Prevention: OCSPP Harmonized Test Guidelines,*
- American Society for Testing and Materials (ATSM): *Environmental Toxicology Standards* (various relevant ecological toxicity tests),
- Organization for Economic Cooperation and Development (OECD): *OECD Guidelines for the Testing of Chemicals, Section 2: Effects on Biotic Systems* (various relevant ecological toxicity tests), and
- International Organization for Standardization (ISO): *TC 147/SC 5 – Biological Methods* (various relevant ecological toxicity tests).

In selecting appropriate toxicity tests from the above mentioned agencies, the ministry expects risk assessors to consider the following criteria:

a) relevance of test species to species present at the site,
b) sensitivity of test species to the contaminant(s) of concern for the site,
c) relevance of test exposure duration,
d) use of test effect endpoints appropriate to the mechanism of toxicity of the contaminant(s) of concern for the site, and
e) extent and representativeness of site phylogenetic diversity when batteries of toxicity tests are to be used.

In addition to the above agencies' ecological toxicity tests, the ministry also recommends consideration of the toxicity tests provided in the following guidance:

- Science Advisory Board for Contaminated Sites in British Columbia: *Report on: Detailed Ecological Risk Assessment (DERA) in British Columbia Technical Guidance. (September 2008),*
- Environment Canada: *FCSAP Supplemental Guidance for Ecological Risk Assessment. Toxicity Test Selection and Interpretation. (March 2010).* Available on request from FCSAP.PASCF@ec.gc.ca, and
- SETAC: *Summary of a SETAC Technical Workshop Porewater Toxicity Testing: Biological, Chemical and Ecological Considerations with a Review of Methods and*

Applications, and Recommendations for Future Areas of Research. (March 2000).

Weight-of-evidence

The ministry recommends the following guidance related to the weight-of-evidence approach in ecological risk assessment:

- Science Advisory Board for Contaminated Sites in British Columbia: *Guidance for a Weight of Evidence Approach in Conducting Detailed Ecological Risk Assessments (DERA) in British Columbia. (June 2010).*

Requirements for human health and ecological risk assessment reports

Technical Bulletin, *"Requirements for Human Health and Ecological Risk Assessment Reports"* provides direction regarding expectations for human health and ecological risk assessment reports submitted for review under the CSR. It is recommended that risk assessors consult the technical bulletin to prevent errors and omissions that may deny or delay approval.

Performance verification plans

Administrative Guidance 14, "*Performance Verification Plans, Contingency Plans and Operations and Maintenance Plans*" describes what these plans are, when they are required, and how they should be prepared, implemented and used. It is recommended that risk assessors consult the document when principal risk controls are included as conditions in Schedule B of a contaminated sites legal instrument.

Note

A performance verification plan must be included in the application for a risk-based standards legal instrument (based on a screening level or detailed risk assessment) for any Type 1B, 2 or 3 site.

Protocol 6 preapprovals

Protocol 6, *"Eligibility of Applications for Review by Approved Professionals"*, requires Director's preapproval of certain risk assessment methodologies before submission of an application recommended for approval by an Approved Professional for a risk-based contaminated sites legal instrument.

Approved Professionals are advised to consult Protocol 6 and ensure that preapprovals have been obtained and documented in any risk assessment to be provided in support of a recommendation by an Approved Professional for a risk-based contaminated sites instrument.

The ministry's preapproval application form and instructions for the form's completion may be obtained from our website.

For more information, contact the Environmental Emergencies and Land Remediation Branch at site@gov.bc.ca.